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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,555	09/25/2000	Veronique M. Braud	SHP-PT059	9366

3624 7590 06/27/2007  
VOLPE AND KOENIG, P.C.  
UNITED PLAZA, SUITE 1600  
30 SOUTH 17TH STREET  
PHILADELPHIA, PA 19103

EXAMINER
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VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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06/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/555,555

Applicant(s)

BRAUD ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-34, 36, 37, 46, 47 and 49-65 is/are pending in the application.
- 4a) Of the above claim(s) 54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-34, 36, 37, 46, 51-53, 55-58, 63 and 64 is/are allowed.
- 6) ☒ Claim(s) 47, 49, 50, 59-62 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB98/03686.

Claims 1-31, 35, 38-45 and 48 have been canceled.

Claims 32-34, 36, 37, 46, 47 and 49-65 are currently pending and are the subject of examination in the present Office Action.

#### *Election/Restrictions*

1. Claim 54 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 54 is a reach-through claim drawn to a method of treatment using "identified compounds." Therapeutic administration of compounds is, distinct from methods of identifying compounds and diagnostic methods previously under consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, **claim 54 stands withdrawn** from consideration as being directed to a non-elected invention. See 37 CFR 1. 142(b) and MPEP § 821.03.

2. **In view of Applicant's amendment and remarks filed April 5, 2007, no outstanding grounds of rejection are maintained.**

The following represents a reinstated ground of rejection that should not have been withdrawn. Accordingly, this rejection is made NON-FINAL.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 47 and 49 are dependent claims each reciting a method “using the identified compounds in medical diagnostic procedures.” These are reach-through claims and lack adequate written descriptive support of the claimed compounds and their use in the claimed procedures.

Base claims 32 and 46 each recite a method for identifying compounds that affect HLA-E binding to CD94, but the specification does not disclose the compounds identified by the method. The claimed method of medical diagnostic procedures thus cannot be practiced based upon the instant specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed medical diagnostic procedures are disclosed, nor has any evidence been shown that such a compound was known. The specification describes assays for screening compounds and even what can be done with any compounds that may potentially be identified through those assays, including medical diagnostic procedures. However, the specification does not disclose just which compounds have the desired characteristic of affecting HLA-E binding to CD94. Without such disclosure, the claimed method cannot be said to have been described. (See *Univ. Rochester v. ...* (CAFC, 2004) 69 USPQ2d 1886)

*Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111) clearly states that “Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” (See *Vas-Cath* at page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016).

The following represents a NEW GROUND of rejection in response to Applicant’s amendment.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 50, 59-62 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation "producing the identified compound" in subsection (v) of the claim. There is insufficient antecedent basis for this limitation in the claim. While the preamble of the claim recites "identified compound," the steps of the claim do not fully provide said identified compound. It is suggested that section (iv) of the claim be amended to recite "HLA-E to the cells" -- thereby providing an identified compound--"; and."

***Conclusion***

5. Claims 32-34, 36, 37, 46, 50-53 and 55-65 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*  
Patent Examiner  
June 18, 2007

*David A. Saunders*  
DAVID A. SAUNDERS  
PRIMARY EXAMINER